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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,014	04/07/2004	Matthew J. Banet	A-0003	3013

48202 7590 08/28/2006

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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3735

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/709,014	<b>Applicant(s)</b> BANET, MATTHEW J.	
	<b>Examiner</b> Patricia C. Mallari	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4,5,7-11,14,18-20 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7-11,14,18-20 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### DETAILED ACTION

This is a final Office action. Any new grounds of rejection were necessitated by the applicants' amendments to the claims

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 5, 7-11, 14, 18, 20, and 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites " a processor that calculates a first time difference between components of the first set of information and the second set of information and a second time difference between the third set of information and at least one of the first and second sets of information and compares the first and second time differences to a mathematical model to calculate a blood pressure". Claim 23 recites, "calculating a first time difference between components of the first and second sets of information, and calculating a second time difference between the third set of information and at least one of the first and second sets of information, and comparing the first and second time differences to a mathematical model to calculate a blood pressure vale". Claim 24

recites, calculating a first time difference between components of the first and second sets of information and processing the third set of information and at least one of the first and second sets of information with the processor by calculating a second time difference between components of the third set of information and at least one of the first second sets of information and comparing the first and second time differences to a mathematical model to calculate a blood pressure value”.

The instant specification lacks description of determining a first and a second time difference and comparing the two to a model to calculate a blood pressure value, as claimed. Paragraph 61 describes using a pair of optical modules in addition to an electrical sensor, and processing data from the modules and sensor to determine blood pressure, but does not describe time differences as claimed. Paragraphs 66 and 69 teach determining a time difference between first information from a first optical module and second information from a second optical module, but is silent as to a time difference between a third information from the electrical signal and any other information. At no point is a comparison between such time differences to a mathematical model to calculate a blood pressure described.

Claims 1, 4, 5, 7-11, 14, 18, 20, and 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As described above, the specification lacks a

description of comparing time differences with a mathematical model to determine a blood pressure value, as claimed in claims 1, 23, and 24. It is therefore unclear how one of ordinary skill in the art would be able to process such information or make and/or use such a processor as claimed in order to determine a blood pressure value by comparison of first and second time differences with an unidentified mathematical model.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,309,916 to Hatschek in view of US Patent No. 5,316,008 to Suga et al. Hatschek teaches a hand-held component 15 configured to be positioned proximal to the patient's skin (col. 9, lines 49-65 of Hatschek). A pressure-delivering component configured to apply pressure to the patient's skin may be provided, wherein a cuff with a closure is configured to apply pressure (col. 9, lines 65-67 of Hatschek). A first optical module 21 is mounted on the hand-held component 15 and comprises a first optical source component 27 and a first optical sensor 29 configured to generate a first set of information while pressure is applied to the patient's skin and radiation emitted from the

optical source is reflected from the patient's skin and detected by the first optical sensor (figs. 1 & 2; col. 10, lines 1-34 of Hatschek). A second optical module 23 is also mounted on the hand-held component 15 and comprises a second optical source component 27 and a second optical sensor 29 configured to generate a second set of information while radiation emitted from the optical source is reflected from the patient's skin and detected by the second optical sensor (figs. 1 & 2; col. 10, lines 1-34 of Hatschek). A processing module 41 is configured to receive the first and second sets of information and comprises a processor that determines a time difference between components of the first set of information and the second set of information and compares the time difference to a mathematical model to calculate a blood pressure value (figs. 1 & 2; col. 10, lines 58-69; col. 13, lines 8-34; col. 16, lines 16-61 of Hatschek). Hatschek lacks the processing module being mounted in the hand-held component.

However, Suga teaches a hand-held device for monitoring a patient's blood pressure comprising a hand-held component (watch) configured to be positioned proximal to the patient's skin, wherein a first optical module and an electric sensor are mounted on the hand-held component and are used to determine a time difference from which a blood pressure measurement is determined by a processing module, also mounted on the hand-held component (figs. 1, 3, 8, 9, 12-14; col. 3, lines 33-68; col. 4, lines 9-26; col. 10, line 28-col. 11, line 14 of Suga). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the invention of Suga with that of Hatschek so as to incorporate the processing module of

Hatschek into a similar hand-held component, since Hatschek teaches an apparatus for determining blood pressure based on the time difference between two pulse-related signals, and Suga teaches that a processing module incorporated into the hand-held component is suitable for such an apparatus configured to determine blood pressure based on the time difference between two pulse-related signals.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Allowable Subject Matter***

No prior art has been applied in a rejection of claims 1, 4, 5, 7-11, 14, 18, 20, and 23-26. Upon resolution of the rejection of these claims under 35 U.S.C. 112, 1<sup>st</sup> paragraph, the prior art will be revisited.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,676,608 to Keren teaches a method and apparatus wherein a first and second optical modules and an electrical sensor are used to measure first, second, and third information, respectively from the patient. A time difference is determined between each of first and second information and first and third information.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PCM

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